

DEC 15 2003

K033740  
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### Summary of Safety and Effectiveness

Device Name: Lorenz Sternal Closure System  
Classification Name: Single/multiple component metallic bone fixation appliances and accessories  
Device Product Code: 87HRS (21 CFR 888.3030)

#### Intended Use:

Lorenz Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including Sternal fixation following Sternotomy and Sternal reconstructive surgical procedures.

#### Description:

The Lorenz Sternal Closure System 2.4 self drilling screws are 2.4 mm in diameter and the lengths may range up to 12mm. The tip of the screw is designed so that a predrilled hole is not required, but may be used.

#### Sterility Information:

The Lorenz Sternal Closure System will be marketed as non-sterile, single use devices. Steam Sterilization recommendations are included in the package insert and can be seen in Attachment I.

#### Substantial Equivalence:

Walter Lorenz considers the Lorenz Sternal Closure System equivalent Lorenz 2.4 Self Drilling Screw (K032228) and Lorenz Sternal Closure System (K011076) TAB 3 includes a substantial equivalence comparison table. TAB 4 includes Premarket clearance (510K) for Lorenz 2.4 Self Drilling Screw (K032228) and Lorenz Sternal Closure System (K011076)

#### Possible risks:

1. Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
2. Nonunion or delayed union, which may lead to breakage of the implant.
3. Migration, bending, fracture or loosening of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Increased fibrous tissue response around the fracture site and/or the implant.
8. Necrosis of bone.
9. Inadequate healing.
10. Selection of screws which are longer than the depth of the sternum may cause possible impingement on structures internal to the chest wall including vessels, pleura and other structures.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Kim Reed  
Senior Regulatory Specialist  
Walter Lorenz Surgical, Inc.  
1520 Tradeport Drive  
Jacksonville, Florida 32218

Re: K033740  
Trade/Device Name: Lorenz Sternal Closure System  
Regulation Numbers: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: II  
Product Codes: HWC  
Dated: November 26, 2003  
Received: November 28, 2003

Dear Ms. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

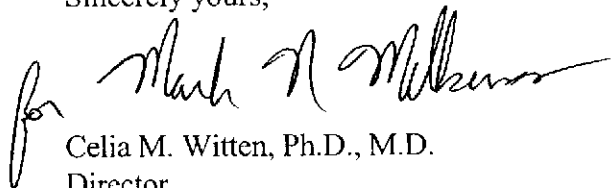
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Mark N. Millman

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**STATEMENT OF INDICATIONS FOR USE**

510(k) Number: K 033740

**Device Name:** Lorenz Sternal Closure System

**Indications For Use:**

Lorenz Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including Sternal fixation following Sternotomy and Sternal reconstructive surgical procedures.

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

for Mark N. McKenna

Restorative  
Surgical Devices

K 033740